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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/082,627	10/29/2001	Peter Kratzch	RDID00112CIPUS	6179

7590 03/17/2004

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EXAMINER

PATTERSON, CHARLES L JR

ART UNIT PAPER NUMBER

1652

DATE MAILED: 03/17/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/082,627	Applicant(s) KRATZCH ET AL.	
	Examiner Charles L. Patterson, Jr.	Art Unit 1652	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 16 September 2002 and 23 February 2004.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-30 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-27 is/are rejected.
- 7) ☒ Claim(s) 28-30 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☒ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☒ Certified copies of the priority documents have been received in Application No. 09/710,197.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

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Reference 33 on the enclosed PTO-1449 has been crossed out. The reference pages are present but there is no indication what journal the reference is in or the date. Without this information one of ordinary skill in the art reading a patent issued from this application would not know how to obtain the reference. If applicants will send another PTO-1449 with only this reference listed and that contains the bibliographic information, the examiner will sign it.

Acknowledgement is made of applicant's claim for foreign priority based on an application filed in Europe on 12/19/00. It is noted, however, that applicant has not filed a certified copy of the European application as required by 35 U.S.C. 119(b). A certified copy of European application 00123512.6 has been filed in parent application 09/710,197 but a copy of 00127294.7 has not been received.

The disclosure is objected to because of the following informalities:

Figures 1, 2 and 4 are objected to as they do not comply with 37 CFR 1.821 - 1.825 because the SEQ ID NO: are not identified. It is suggested that the SEQ ID NO: be added to the description on page 6 and not to the drawings themselves.

Appropriate correction is required.

Claims 28-30 are objected to under 37 CFR 1.75(c) as being in improper form because a multiple dependent claim should depend only one other claim in the alternative and a multiple dependent claim should not depend to another multiple dependent claim. See MPEP § 608.01(n). Accordingly, the claims have not been further treated on the merits. Claim 28 refers to "any of the

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preceding claims" and should refer to "any one of the preceding claims" to be proper. Claim 30 depends from another multiple dependent claim, namely claim 28.

Claims 1, 6, 8, 9, 13, 16, 18, 20 and 27 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1 and 6 are confusing and apparently incorrect in the recitation of "EC 1.1.99.17". This enzyme has been transferred to 1.1.5.2, as noted in the enclosed NiceZyme entry from ExPASy.

Claims 1, 6, 8, 9, 13, 16, 18 and 20 are indefinite in the recitation of "PQQ". Abbreviations should be avoided in patent claims and should be defined in at least the first claim in which they appear. The recitation of pyrroloquinoline quinone (PQQ)-dependent..." in claim 1 would overcome this rejection.

Claim 8 is incorrect in the recitation of "A. baumannii", which should be "A. *baumanni*". The claim is also indefinite and confusing in the recitation of "is isolated from a strain of the Acinetobacter species group consisting of A. *calcoaceticus* and A. *baumanni*". The instant recitation is drawn to "a strain" and then lists two strains. A recitation of "is isolated from a strain of Acinetobacter selected from the group consisting of A. *calcoaceticus* and A. *baumanni*", or some similar recitation would overcome this rejection.

Claims 9 and 13 are indefinite and do not conform with the sequence rules (37 CFR 1.821 - 1.825) in that the sequence of the mature "A. *calcoace-*

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ticus" does not have its SEQ ID NO: listed. For purposes of this examination it is presumed that it is SEQ ID NO:24.

Claim 9 is indefinite and confusing in the recitation of "selected from the group comprising positions 348 and 428". This is not a proper recitation of a Markush group, which would be "selected from the group consisting of positions 348 and 428". It is not clear what the "group" is as it "comprises" only two members and could have an unlimited number of other members.

Claims 13 is confusing and incorrect in the recitation of "438." in line 4. Only one period should appear in patent claims. The claim is also indefinite in the recitation of "T348 or N428 is replaced". What are the residues replaced with. This recitation reads on replacing T348 or N428 with any number of amino acids or even with something other than amino acids.

Claims 16, 18 and 20 are confusing and inconsistent in the recitation of "WPXaaVAPS", "TAGXaaVQK" and "ADGXaaNGL", respectively. The instant recitations mix the one letter abbreviations of amino acids with the three letter abbreviations (Xaa). The abbreviations system used should be consistent and one or the other set of abbreviation should be used.

Claim 27 is indefinite in the recitation of "variants with the construct of claim 26...". There is no antecedent basis for "construct of claim 26 and exactly how the construct of claim 26 is to be used is not delineated. A recitation of "variants comprising culturing a host cell containing the expression vector of claim 26" or some similar recitation would overcome this rejection.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and

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use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-27 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for mutants from specific PQQ-dependent glucose dehydrogenase having particular changes in the amino acid sequence, does not reasonably provide enablement for claims of the scope of the instant claims. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to the invention commensurate in scope with these claims make and/or use the claimed invention.

The instant claims are not limited to a particular PQQ-dependent glucose dehydrogenase or to a particular source of the enzyme, and are not limited to particular mutations or they are too broad to cover the requirement in claim 1 that the activity be at least two-fold higher with glucose than with another sugar. The specification does not teach one of ordinary skill in the art how to make all of the enzymes and/or polynucleotides of the instant claims, only how to make the PQQ-dependent glucose dehydrogenase from *A. calcoaceticus* having particular amino acid changes. Exactly what affect a change in a particular amino acid, or the corresponding polynucleotide encoding it, will have on an enzyme's activity is not predictable with any certainty. Therefore the claims should be limited to the embodiments taught in the instant specification.

It is noted that Table 1 does not show the effect of a mutation at only position 428, T348A is shown to have 67% as much activity with maltose as glucose, a T348S mutation is not shown alone and an mutation of position 428 to any amino acid alone is not shown. Likewise, all of the possible combinations of claims 11 and 13-15 are not shown. Claims 16-21 read on any PQQ-dependent glucose dehydrogenase comprising the indicated short sequences given

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in the claims and the specification does not teach one of ordinary skill how to make all of the embodiments of these claims.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-7 and 22-26 are rejected under 35 U.S.C. 102(b) as being anticipated by either of Cleton-Jansen, et al. (U) or Sode (4).

Cleton-Jansen, et al. teach a form of PQQ-dependent glucose dehydrogenase that will only oxidize glucose (P1) and one that will also oxidize maltose (P2). The reference characterizes P2 as a mutant of P1 but since all proteins in nature are constantly undergoing mutation, P1 could be characterized as a mutant of P2. Soda teaches in Table 1 a series of mutants of PQQ-

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dependent glucose dehydrogenase that meet the requirements of the instant claims. All of the mutant proteins have at least two fold higher activity against glucose than maltose. It is maintained that the enzyme taught by the instant references are the same as those of the instant claims, absent very convincing proof to the contrary. The polynucleotide sequence is taught in Fig. 3 of Cleton-James and the nucleotide sequence of Sode is known since it is a known variation of a known nucleotide. The patent office does not have facilities to assay enzymes and see what characteristics they have.

Claims 1-7 and 22-27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cleton-Jansen, et al. (U) or Sode (4).

The instant references are characterized *supra*. It is maintained that if the vector of claim 26 could not be used in a cell-free system then one of ordinary skill in the art would know how to modify it so that it would using the general knowledge in the prior art. Therefore, it would have been obvious to one of ordinary skill in the art to produce a vector that could be used in either a host cell or cell-free system in view of the instant reference and the general knowledge in the art. The motivation would have been to produce the enzyme so as to further study it or to use it in glucose detection.

Claims 1-5, 13-27 are rejected under 35 U.S.C. 102(b) as being anticipated by Cleton-Jansen, et al. (15). The instant reference teaches in Table 2 the mutant PP2403 of PQQ-dependent glucose dehydrogenase, which has 0.3 units/ml of activity against glucose and 0.0 units/ml activity against maltose. All of the other requirements of the instant claims are taught by the reference.

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Claim 16 is rejected under 35 U.S.C. 102(b) as being anticipated by Murphy, et al. (V). The instant reference teaches a protein with SEQ ID NO:1 where XAA is not threonine. Since the reference meets the requirements of the claim as to sequence, it meets the requirements of the entire claim since it does not matter what the protein is called.

Claim 18 is rejected under 35 U.S.C. 102(b) as being anticipated by Lamelp. et al. (W). The instant reference teaches a protein with SEQ ID NO:2 where XAA is not asparagine. Since the reference meets the requirements of the claim as to sequence, it meets the requirements of the entire claim since it does not matter what the protein is called.

Claims 20-21 are rejected under 35 U.S.C. 102(b) as being anticipated by Granger, et al. (X). The instant reference teaches a protein with SEQ ID NO:3 where XAA is alanine. Since the reference meets the requirements of the claim as to sequence, it meets the requirements of the entire claim since it does not matter what the protein is called.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Charles L. Patterson, Jr., PhD, whose telephone number is 571-272-0936. The examiner can normally be reached on Monday - Friday from 7:30 to 4:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapura Achutamurthy, can be reached on 571-272-0928. The fax phone number for the organization where this application or proceeding is assigned is 703-308-4242.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Charles L. Patterson, Jr.
Primary Examiner
Art Unit 1652

Patterson
March 12, 2004